

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

----- X
AMALIA FASANO and NICOLA FASANO,

Plaintiffs,

-against-

TYCO HEALTHCARE GROUP LP d/b/a
COVIDIEN; SOFRADIM PRODUCTION SAS;
and John Does 1-50,

Defendants.
----- X

Case No. 1: 13-cv-03083

**COVIDIEN LP'S ANSWER AND
AFFIRMATIVE DEFENSES TO
PLAINTIFFS' COMPLAINT**

COVIDIEN LP'S ANSWER TO PLAINTIFFS' COMPLAINT

Defendant Covidien LP (formerly known as "Tyco Healthcare Group LP) by and through undersigned counsel, hereby files its Answer and Affirmative Defenses ("Answer") to Plaintiffs' Complaint ("Complaint") containing allegations against the Parietex Composite product. Covidien LP generally denies all factual allegations contained in Plaintiffs' Complaint that pertain to Covidien LP except those specifically admitted herein, and reserve any and all defenses now available or that may become available in the future. In further response to the numbered allegations contained in Plaintiffs' Complaint, Covidien LP answers as follows:

1. Covidien LP is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 of the Complaint and, therefore, denies the same.

2. Covidien LP is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of the Complaint and, therefore, denies the same.

3. Covidien LP denies the allegations in Paragraph 3 of Plaintiffs' Complaint, except admits that Covidien LP (formerly known as "Tyco Healthcare Group LP") is a Delaware limited

partnership with its principal place of business in Massachusetts and is registered to conduct business in Massachusetts.

4. The allegations in Paragraph 4 of Plaintiffs' Complaint are directed to a party or entity other than Covidien LP, and accordingly no response is required. However, to the extent those allegations purport to cast liability either directly or indirectly upon Covidien LP, Covidien LP denies the same.

5. The allegations in Paragraph 5 of Plaintiffs' Complaint are directed to a party or entity other than Covidien LP, and accordingly no response is required. However, to the extent those allegations purport to cast liability either directly or indirectly upon Covidien LP, Covidien LP denies the same.

6. The allegations in Paragraph 6 of Plaintiffs' Complaint do not contain factual allegations directed to any party or entity, and accordingly no response is required.

7. Covidien LP denies the allegations in Paragraph 7 of Plaintiffs' Complaint.

8. Covidien LP denies the allegations in Paragraph 8 of Plaintiffs' Complaint.

9. Covidien LP denies the allegations in Paragraph 9 of Plaintiffs' Complaint.

JURISDICTION AND VENUE

10. The allegations in Paragraph 10 of Plaintiffs' Complaint constitute legal conclusions to which no response is required.

11. Covidien LP admits plaintiffs are alleging damages in excess of \$75,000. The remaining allegations in Paragraph 11 of Plaintiffs' Complaint constitute legal conclusions to which no response is required.

12. The allegations in Paragraph 12 of Plaintiffs' Complaint constitute legal conclusions to which no response is required.

STATEMENT OF FACTS

13. Covidien LP denies the allegations in Paragraph 13 of Plaintiffs' Complaint except responds that the 510(k) clearance referenced therein is a document that speaks for itself.

14. Covidien LP admits the allegations in Paragraph 14 of Plaintiffs' Complaint.

15. Covidien LP admits the allegations in Paragraph 15 of Plaintiffs' Complaint.

16. Covidien LP admits the allegations in Paragraph 16 of Plaintiffs' Complaint.

17. Covidien LP admits the allegations in Paragraph 17 of Plaintiffs' Complaint.

18. Covidien LP denies the allegations in Paragraph 18 of Plaintiffs' Complaint.

19. Covidien LP denies the allegations in Paragraph 19 of Plaintiffs' Complaint.

20. Covidien LP denies the allegations in Paragraph 20 of Plaintiffs' Complaint.

21. Covidien LP denies the allegations in Paragraph 21 of Plaintiffs' Complaint.

22. Covidien LP admits the allegations in Paragraph 22 of Plaintiffs' Complaint.

23. Covidien LP admits the allegations in Paragraph 23 of Plaintiffs' Complaint.

24. Covidien LP denies the allegations in Paragraph 24 of Plaintiffs' Complaint.

25. Covidien LP denies the allegations in Paragraph 25 of Plaintiffs' Complaint.

26. Covidien LP denies the allegations in Paragraph 26 of Plaintiffs' Complaint.

27. Covidien LP denies the allegations in Paragraph 27 of Plaintiffs' Complaint.

28. Covidien LP denies the allegations in Paragraph 28 of Plaintiffs' Complaint.

29. Covidien LP admits that the collagen used in Parietex is hydrophilic and is meant to minimize tissue attachment, but denies the remaining allegations in Paragraph 29 of Plaintiffs' Complaint.

30. Covidien LP denies the allegations in Paragraph 30 of Plaintiffs' Complaint.

31. Covidien LP denies the allegations in Paragraph 31 of Plaintiffs' Complaint.

32. Covidien LP denies the allegations in Paragraph 32 of Plaintiffs' Complaint.

33. Covidien LP denies the allegations in Paragraph 33 of Plaintiffs' Complaint

except responds that the July 13, 2011 communication issued by FDA is a document that speaks for itself. Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

34. Covidien LP denies the allegations in Paragraph 34 of Plaintiffs' Complaint except responds that the December 2011 Joint Committee Opinion is a document that speaks for itself. Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

35. Covidien LP denies the allegations in Paragraph 35 of Plaintiffs' Complaint except responds that the December 2011 Joint Committee Opinion is a document that speaks for itself. Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

36. Covidien LP denies the allegations in Paragraph 36 of Plaintiffs' Complaint except responds that communication issued by FDA is a document that speaks for itself. Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

37. Covidien LP denies the allegations in Paragraph 37 of Plaintiffs' Complaint except responds that the White Paper issued by FDA is a document that speaks for itself. Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

38. Covidien LP denies the allegations in Paragraph 38 of Plaintiffs' Complaint except responds that the White Paper issued by FDA is a document that speaks for itself. Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

39. Covidien LP denies the allegations in Paragraph 39 of Plaintiffs' Complaint except responds that the White Paper issued by FDA is a document that speaks for itself.

Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

40. Covidien LP denies the allegations in Paragraph 40 of Plaintiffs' Complaint except responds that the White Paper issued by FDA is a document that speaks for itself. Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

41. Covidien LP denies the allegations in Paragraph 41 of Plaintiffs' Complaint except responds that the White Paper issued by FDA is a document that speaks for itself. Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

42. Covidien LP denies the allegations in Paragraph 42 of Plaintiffs' Complaint except responds that the White Paper issued by FDA is a document that speaks for itself. Covidien LP further denies that said document in any way refers to or references the product at issue in this case.

43. Covidien LP denies the allegations in Paragraph 43 of Plaintiffs' Complaint. Covidien LP further denies that the FDA communication referenced in Paragraph 43 of Plaintiffs' Complaint refers to or references the product at issue in this case.

44. Covidien LP denies the allegations in Paragraph 44 of Plaintiffs' Complaint. Covidien LP further denies that the Joint Committee Opinion referenced in Paragraph 44 of Plaintiffs' Complaint refers to or references the product at issue in this case.

45. Covidien LP denies the allegations in Paragraph 45 of Plaintiffs' Complaint.

46. Covidien LP denies the allegations in Paragraph 46 of Plaintiffs' Complaint.

47. Covidien LP denies the allegations in Paragraph 47 of Plaintiffs' Complaint.

48. Covidien LP denies the allegations in Paragraph 48 of Plaintiffs' Complaint.

49. Covidien LP denies the allegations in Paragraph 49 of Plaintiffs' Complaint.

50. Covidien LP denies the allegations in Paragraph 50 of Plaintiffs' Complaint.

51. Covidien LP denies the allegations in Paragraph 51 of Plaintiffs' Complaint.

52. Covidien LP denies the allegations in Paragraph 52 of Plaintiffs' Complaint.

53. Covidien LP denies the allegations in Paragraph 53 of Plaintiffs' Complaint.

54. Covidien LP denies the allegations in Paragraph 54 of Plaintiffs' Complaint.

55. Covidien LP denies the allegations in Paragraph 55 of Plaintiffs' Complaint.

56. Covidien LP denies the allegations in Paragraph 56 of Plaintiffs' Complaint.

57. Covidien LP denies the allegations in Paragraph 57 of Plaintiffs' Complaint.

58. Covidien LP denies the allegations in Paragraph 58 of Plaintiffs' Complaint.

59. Covidien LP denies the allegations in Paragraph 59 of Plaintiffs' Complaint.

60. Covidien LP denies the allegations in Paragraph 60 of Plaintiffs' Complaint.

61. Covidien LP denies the allegations in Paragraph 61 of Plaintiffs' Complaint.

62. Covidien LP denies the allegations in Paragraph 62 of Plaintiffs' Complaint.

63. Covidien LP denies the allegations in Paragraph 63 of Plaintiffs' Complaint.

64. Covidien LP denies the allegations in Paragraph 64 of Plaintiffs' Complaint.

65. Covidien LP denies the allegations in Paragraph 65 of Plaintiffs' Complaint.

66. Covidien LP is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 66 of the Complaint and, therefore, denies the same.

67. Covidien LP denies the allegations in Paragraph 67 of Plaintiffs' Complaint.

68. Covidien LP denies the allegations in Paragraph 68 of Plaintiffs' Complaint.

69. Covidien LP denies the allegations in Paragraph 69 of Plaintiffs' Complaint.

70. Covidien LP denies the allegations in Paragraph 70 of Plaintiffs' Complaint.

71. Covidien LP denies the allegations in Paragraph 71 of Plaintiffs' Complaint.

72. Covidien LP denies the allegations in Paragraph 72 of Plaintiffs' Complaint.

73. Covidien LP is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 73 of the Complaint and, therefore, denies the same.

74. Covidien is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 74 of the Complaint and, therefore, denies the same.

75. Covidien LP denies the allegations in Paragraph 75 of Plaintiffs' Complaint.

76. Covidien LP denies the allegations in Paragraph 76 of Plaintiffs' Complaint.

77. Covidien LP denies the allegations in Paragraph 77 of Plaintiffs' Complaint.

78. Covidien LP denies the allegations in Paragraph 78 of Plaintiffs' Complaint.

79. Covidien LP denies the allegations in Paragraph 79 of Plaintiffs' Complaint.

80. Covidien LP denies the allegations in Paragraph 80 of Plaintiffs' Complaint.

81. Covidien LP denies the allegations in Paragraph 81 of Plaintiffs' Complaint.

82. Covidien LP denies the allegations in Paragraph 82 of Plaintiffs' Complaint.

83. Covidien LP denies the allegations in Paragraph 83 of Plaintiffs' Complaint.

84. Covidien LP denies the allegations in Paragraph 84 of Plaintiffs' Complaint.

85. Covidien LP denies the allegations in Paragraph 85 of Plaintiffs' Complaint.

86. Covidien LP is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 86 of the Complaint and, therefore, denies the same.

87. Covidien LP is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 87 of the Complaint and, therefore, denies the

same.

88. Covidien LP is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 88 of the Complaint and, therefore, denies the same.

89. Covidien LP is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 89 of the Complaint and, therefore, denies the same.

90. Covidien LP denies the allegations in Paragraph 90 of Plaintiffs' Complaint.

91. Covidien LP is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 91 of the Complaint and, therefore, denies the same.

92. Covidien LP denies the allegations in Paragraph 92 of Plaintiffs' Complaint.

CAUSES OF ACTION
AS FOR THE FIRST CAUSE OF ACTION
(NEGLIGENCE)

93. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 93 of Plaintiffs' Complaint contains new allegations, Covidien LP denies the same.

94. The allegations in Paragraph 94 of Plaintiffs' Complaint constitute legal conclusions to which no response is required.

95. Covidien LP denies the allegations in Paragraph 95 of Plaintiffs' Complaint.

96. Covidien LP denies the allegations in Paragraph 96 of Plaintiffs' Complaint.

Further, responding to the unnumbered Paragraph beginning "Wherefore," Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

**FOR THE SECOND CAUSE OF ACTION
(DESIGN DEFECT)**

97. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 97 of Plaintiffs' Complaint contains new allegations, Covidien LP denies the same.

98. Covidien LP denies the allegations in Paragraph 98 of Plaintiffs' Complaint.

99. Covidien LP denies the allegations in Paragraph 99 of Plaintiffs' Complaint.

100. Covidien LP denies the allegations in Paragraph 100 of Plaintiffs' Complaint.

101. Covidien LP denies the allegations in Paragraph 101 of Plaintiffs' Complaint.

102. Covidien LP denies the allegations in Paragraph 102 of Plaintiffs' Complaint.

103. Covidien LP denies the allegations in Paragraph 103 of Plaintiffs' Complaint.

104. Covidien LP denies the allegations in Paragraph 104 of Plaintiffs' Complaint.

105. Covidien LP denies the allegations in Paragraph 105 of Plaintiffs' Complaint.

106. Covidien LP denies the allegations in Paragraph 106 of Plaintiffs' Complaint.

107. Covidien LP denies the allegations in Paragraph 107 of Plaintiffs' Complaint.

Further, responding to the unnumbered Paragraph beginning "Wherefore," Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

**AS FOR THE THIRD CAUSE OF ACTION
(MANUFACTURING DEFECT)**

108. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 108 of Plaintiffs' Complaint contains new allegations, Covidien LP denies the same.

109. Covidien LP denies the allegations in Paragraph 109 of Plaintiffs' Complaint.

110. Covidien LP denies the allegations in Paragraph 110 of Plaintiffs' Complaint.

111. Covidien LP denies the allegations in Paragraph 111 of Plaintiffs' Complaint.

Further, responding to the unnumbered Paragraph beginning “Wherefore,” Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

**AS FOR THE FOURTH CAUSE OF ACTION
(FAILURE TO WARN)**

112. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 112 of Plaintiffs’ Complaint contains new allegations, Covidien LP denies the same.

113. Covidien LP denies the allegations in Paragraph 113 of Plaintiffs’ Complaint.

114. The allegations in Paragraph 114 of Plaintiffs’ Complaint constitute legal conclusions to which no response is required.

115. Covidien LP denies the allegations in Paragraph 115 of Plaintiffs’ Complaint.

116. Covidien LP denies the allegations in Paragraph 116 of Plaintiffs’ Complaint.

117. Covidien LP denies the allegations in Paragraph 117 of Plaintiffs’ Complaint.

118. Covidien LP denies the allegations in Paragraph 118 of Plaintiffs’ Complaint.

119. Covidien LP denies the allegations in Paragraph 119 of Plaintiffs’ Complaint.

120. Covidien LP denies the allegations in Paragraph 120 of Plaintiffs’ Complaint.

121. Covidien LP denies the allegations in Paragraph 121 of Plaintiffs’ Complaint.

122. Covidien LP denies the allegations in Paragraph 122 of Plaintiffs’ Complaint.

123. Covidien LP denies the allegations in Paragraph 123 of Plaintiffs’ Complaint.

124. Covidien LP denies the allegations in Paragraph 124 of Plaintiffs’ Complaint.

125. Covidien LP denies the allegations in Paragraph 125 of Plaintiffs’ Complaint.

Further, responding to the unnumbered Paragraph beginning “Wherefore,” Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

**AS FOR THE FIFTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)**

126. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 126 of Plaintiffs' Complaint contains new allegations, Covidien LP denies the same.

127. Covidien LP denies the allegations in Paragraph 127 of Plaintiffs' Complaint.

128. Covidien LP denies the allegations in Paragraph 128 of Plaintiffs' Complaint.

129. Covidien LP denies the allegations in Paragraph 129 of Plaintiffs' Complaint.

130. Covidien LP denies the allegations in Paragraph 130 of Plaintiffs' Complaint.

131. Covidien LP denies the allegations in Paragraph 131 of Plaintiffs' Complaint.

132. Covidien LP denies the allegations in Paragraph 132 of Plaintiffs' Complaint.

Further, responding to the unnumbered Paragraph beginning "Wherefore," Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

**AS FOR THE SIXTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY)**

133. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 133 of Plaintiffs' Complaint contains new allegations, Covidien LP denies the same.

134. Covidien LP denies the allegations in Paragraph 134 of Plaintiffs' Complaint.

135. Covidien LP denies the allegations in Paragraph 135 of Plaintiffs' Complaint.

136. Covidien LP denies the allegations in Paragraph 136 of Plaintiffs' Complaint.

137. Covidien LP denies the allegations in Paragraph 137 of Plaintiffs' Complaint.

138. Covidien LP denies the allegations in Paragraph 138 of Plaintiffs' Complaint.

139. Covidien LP denies the allegations in Paragraph 139 of Plaintiffs' Complaint.

Further, responding to the unnumbered Paragraph beginning "Wherefore," Covidien LP

denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

**AS FOR THE SEVENTH CAUSE OF ACTION
(FRAUD)**

140. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 140 of Plaintiffs' Complaint contains new allegations, Covidien LP denies the same.

141. Covidien LP denies the allegations in Paragraph 141 of Plaintiffs' Complaint.

142. Covidien LP denies the allegations in Paragraph 142 of Plaintiffs' Complaint.

143. Covidien LP denies the allegations in Paragraph 143 of Plaintiffs' Complaint.

144. Covidien LP denies the allegations in Paragraph 144 of Plaintiffs' Complaint.

145. Covidien LP denies the allegations in Paragraph 145 of Plaintiffs' Complaint.

Further, responding to the unnumbered Paragraph beginning "Wherefore," Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

**AS FOR THE EIGHTH CAUSE OF ACTION
(UNJUST ENRICHMENT)**

146. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 146 of Plaintiffs' Complaint contains new allegations, Covidien LP denies the same.

147. Covidien LP denies the allegations in Paragraph 147 of Plaintiffs' Complaint.

148. Covidien LP denies the allegations in Paragraph 148 of Plaintiffs' Complaint.

149. Covidien LP denies the allegations in Paragraph 149 of Plaintiffs' Complaint.

Further, responding to the unnumbered Paragraph beginning "Wherefore," Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

**AS FOR THE NINTH CAUSE OF ACTION
(LOSS OF CONSORTIUM)**

150. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 150 of Plaintiffs' Complaint contains new allegations, Covidien LP denies the same.

151. Covidien LP denies the allegations in Paragraph 151 of Plaintiffs' Complaint.

152. Covidien LP denies the allegations in Paragraph 152 of Plaintiffs' Complaint.

Further, responding to the unnumbered Paragraph beginning "Wherefore," Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

**AS FOR THE TENTH CAUSE OF ACTION
(PUNITIVE DAMAGES)**

153. Covidien LP hereby repeats and reasserts all responses contained in this Answer as if fully set forth herein. To the extent the Paragraph numbered 153 of Plaintiffs' Complaint contains new allegations, Covidien LP denies the same.

154. Covidien LP denies the allegations in Paragraph 154 of Plaintiffs' Complaint.

155. Covidien LP denies the allegations in Paragraph 155 of Plaintiffs' Complaint.

Further, responding to the unnumbered Paragraph beginning "Wherefore," Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

PRAYER FOR RELIEF

Responding to the unnumbered Paragraph beginning "Wherefore," Covidien LP denies the allegations contained therein, and denies that Plaintiffs are entitled to any relief requested.

Further, Covidien LP denies each and every allegation contained in the Complaint which has not been expressly admitted herein.

AFFIRMATIVE DEFENSES

Having answered the allegations of the Plaintiffs' Complaint and having denied any liability whatsoever, Covidien LP further denies any allegations that have not been expressly admitted, and asserts the following defenses in response to the allegations in Plaintiffs' Complaint.

FIRST AFFIRMATIVE DEFENSE

156. Plaintiffs' Complaint, and each Count thereof, fails to state a claim upon which relief can be granted against Covidien LP.

SECOND AFFIRMATIVE DEFENSE

157. Plaintiffs' claims are barred for failure to join necessary and/or indispensable parties.

THIRD AFFIRMATIVE DEFENSE

158. Plaintiffs' claims are barred by the applicable statutes of limitation and/or repose.

FOURTH AFFIRMATIVE DEFENSE

159. Plaintiffs' claims are barred by the doctrines of equitable estoppel, waiver, and laches.

FIFTH AFFIRMATIVE DEFENSE

160. Covidien LP pleads the provisions of Article 50 of the C.P.L.R.

SIXTH AFFIRMATIVE DEFENSE

161. Plaintiffs' claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed with the generally recognized, reasonably available, and reliable state of knowledge when the product was manufactured and marketed.

SEVENTH AFFIRMATIVE DEFENSE

162. All acts of Covidien LP at the time of the alleged manufacture, sale, and/or distribution of the product at issue conformed to the state-of-the-art.

EIGHTH AFFIRMATIVE DEFENSE

163. Plaintiffs' claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed with industry custom/usage standards and/or legislative/administrative/regulatory standards.

NINTH AFFIRMATIVE DEFENSE

164. Plaintiffs' claims are barred, in whole or in part, by the Comment (k) and/or Comment (j) of § 402A of the Restatement (Second) of Torts and by §§ 4 and 6 of the Restatement (Third) of Torts (Product Liability).

TENTH AFFIRMATIVE DEFENSE

165. The product at issue is neither defective nor unreasonably dangerous because it is a medical device falling within what is commonly known as Comment (j), Restatement (Second) of Torts § 402A, and comparable provisions of the Restatement (Third) of Torts (Products Liability), in that the product at issue was, at all times material to Plaintiffs' Complaint, reasonably safe and reasonably fit for its intended use, and the warnings and instructions accompanying the product at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate.

ELEVENTH AFFIRMATIVE DEFENSE

166. If Plaintiffs have been damaged, which Covidien LP denies, their damages were caused by abuse, misuse, user error and/or modification of the product at issue.

TWELFTH AFFIRMATIVE DEFENSE

167. The design complained of in Plaintiffs' Complaint, the alleged defects of the product, and/or any alternative design claimed by Plaintiffs were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the product at issue was designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

THIRTEENTH AFFIRMATIVE DEFENSE

168. Plaintiffs' claims are barred because Covidien LP did not owe a legal duty to Plaintiffs. If Covidien LP owed Plaintiffs a legal duty, it did not breach that duty.

FOURTEENTH AFFIRMATIVE DEFENSE

169. Plaintiffs' claims are barred because any alleged breach of duty by Covidien LP, which it denies, was not a proximate cause of Plaintiffs' damages.

FIFTEENTH AFFIRMATIVE DEFENSE

170. If Plaintiffs has been damaged, which Covidien LP denies, their damages were caused by the negligence or fault of Plaintiffs.

SIXTEENTH AFFIRMATIVE DEFENSE

171. If Plaintiffs have been damaged, which Covidien LP denies, their damages were caused by the negligence or fault of persons and/or entities for whose conduct Covidien LP is not legally responsible.

SEVENTEENTH AFFIRMATIVE DEFENSE

172. If Plaintiffs have been damaged, which Covidien LP denies, the negligence or

fault of Plaintiffs must be compared, reducing or completely barring Plaintiffs' alleged right to recover against Covidien LP.

EIGHTEENTH AFFIRMATIVE DEFENSE

173. If Plaintiffs have been damaged, which Covidien LP denies, the negligence or fault of persons and/or entities for whose conduct Covidien LP is not legally responsible must be compared, reducing or completely barring Plaintiffs' alleged right to recover against Covidien LP.

NINETEENTH AFFIRMATIVE DEFENSE

174. If Plaintiffs have been damaged, which Covidien LP denies, the negligence or fault of Plaintiffs constitute the sole, intervening, and superseding cause of Plaintiffs' alleged damages.

TWENTIETH AFFIRMATIVE DEFENSE

175. If Plaintiffs have been damaged, which Covidien LP denies, the negligence or fault of persons and/or entities for whose conduct Covidien LP is not legally responsible constitutes the sole, intervening, and superseding cause of Plaintiffs' alleged damages.

TWENTY-FIRST AFFIRMATIVE DEFENSE

176. If Plaintiffs have been damaged, which Covidien LP denies, the actions of persons or entities for whose conduct Covidien LP is not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the product and other independent causes, constitute an intervening and superseding cause of Plaintiffs' alleged damages.

TWENTY-SECOND AFFIRMATIVE DEFENSE

177. If Plaintiffs have been damaged, which Covidien LP denies, their damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Covidien LP is not legally responsible.

TWENTY-THIRD AFFIRMATIVE DEFENSE

178. If Plaintiffs have been damaged, which Covidien LP denies, their damages were caused by Plaintiff's unrelated pre-existing or co-existing medical conditions.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

179. Plaintiffs' claims are barred by the consent of Plaintiffs.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

180. If Plaintiffs have been damaged, which Covidien LP denies, any recovery by Plaintiffs is barred by the doctrine of assumption of risk.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

181. If Plaintiffs have been damaged, which Covidien LP denies, any recovery by Plaintiffs is barred to the extent Plaintiffs voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent Plaintiffs have failed to mitigate their alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

182. The federal government, through federal statutes such as the Federal Food Drug & Cosmetic Act, has preempted the field of law applicable to the product at issue. The product referred to in the Complaint was and is controlled by federal law, which governs the manufacture, distribution, and sale of said devices at all times. Plaintiffs' claims are thus preempted in whole or in part such that they fail to state a cause of action upon which relief can be granted.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

183. Plaintiffs' claims are barred by the learned intermediary, informed intermediary, bulk supplier, and/or sophisticated user doctrines.

TWENTY-NINETH AFFIRMATIVE DEFENSE

184. If Plaintiffs recover from Covidien LP, it is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiffs' alleged damages.

THIRTIETH AFFIRMATIVE DEFENSE

185. Covidien LP specifically pleads all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

THIRTY-FIRST AFFIRMATIVE DEFENSE

186. If Plaintiffs sustained damages as alleged in Plaintiffs' Complaint, which Covidien LP denies, the application of joint and several liability law violates Covidien LP's constitutional rights under the Fifth, Sixth, Eighth and Fourteenth Amendments of the United States Constitution and the New York Constitution, in one or more of the following respects:

- (a) The application of joint and several liability is equivalent to the imposition of an excessive fine or cruel and unusual punishment;

- (b) The application of joint and several liability exposes Covidien LP to multiple punishments and fines for the same act;
- (c) The application of joint and several liability discriminates against Covidien LP in that Covidien LP may be held legally responsible for paying damage awards entered against other defendants depending solely on the status or material wealth of various defendants, thereby denying equal protection under the law;
- (d) The application of joint and several liability without informing the jury of the effect of joint and several liability violates the equal protection and substantive and procedural due process requirements of both the New York Constitution and the United States Constitution; and
- (e) The application of joint and several liability constitutes an impermissible burden upon interstate commerce and otherwise violates Covidien LP's equal protection and due process rights.

THIRTY-SECOND AFFIRMATIVE DEFENSE

187. Plaintiffs' claims are or may be barred, in whole or in part, to the extent that Plaintiffs have released, settled with, entered into an accord and satisfaction, or otherwise compromised their claims. Covidien LP is entitled to a set-off for the entire amount of proceeds Plaintiffs have or may recover from other sources.

THIRTY-THIRD AFFIRMATIVE DEFENSE

188. Plaintiffs' claim for breach of implied warranty must fail because the product was not used for its ordinary purpose.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

189. Plaintiffs' claim for breach of warranty is barred because Plaintiffs did not first give notice of any alleged defect of the product to Covidien LP.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

190. Plaintiffs' breach of warranty claim is barred because there is a lack of privity between Plaintiffs and Covidien LP.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

191. Plaintiffs' claim for breach of implied warranty must fail because Plaintiffs did

not rely on the implied warranty, if any.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

192. Plaintiffs' claim for breach of warranty is barred because any alleged breach of duty by Covidien LP, which Covidien LP denies, was not a proximate cause of Plaintiffs' damages.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

193. Plaintiffs' claim for breach of warranty is barred because no implied warranties of fitness for a particular purpose or for merchantability existed for any transaction alleged to have been entered into by Covidien LP, or any warranty or cause of action based upon a warranty was waived by Plaintiffs.

THIRTY-NINETH AFFIRMATIVE DEFENSE

194. If Plaintiffs seek to recover for the cost of medical care, loss of earnings or other economic loss, such past or future costs or expenses was or will, with reasonable certainty, be replaced or indemnified in whole or in part, from a collateral source; by reason of such, any award obtained by Plaintiffs must be reduced by the amount obtained from collateral sources.

FORTIETH AFFIRMATIVE DEFENSE

195. The relative culpability of each party who is or may be liable for the damages alleged by Plaintiffs in this action should be determined in accordance with the decisional and statutory law of the State of New York and the equitable share of each party's liability for contribution should be determined and apportioned in accordance with the relative liability, if any, of each such party pursuant to Article 14 of the CPLR.

FORTY-FIRST AFFIRMATIVE DEFENSE

196. If Plaintiffs seek to recover any damages for "non-economic loss" as defined by CPLR § 1600 *et seq.* and the liability of the answering defendant is found to be 50% or less than the total liability assigned to all parties liable, then the liability of the answering defendant to

Plaintiffs for such “non-economic loss” shall not exceed the equitable share of the defendant, and in accordance with the relative culpability of each party causing or contributing to the total liability for such “non-economic loss.”

FORTY-SECOND AFFIRMATIVE DEFENSE

197. Covidien LP is entitled to a set-off, should any damages be awarded against it, for the entire amount of damages or settlement amounts recovered from other sources, in accordance with C.P.L.R. § 4545.

FORTY-THIRD AFFIRMATIVE DEFENSE

198. Covidien LP specifically incorporates by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

FORTY-FOURTH AFFIRMATIVE DEFENSE

199. Plaintiffs’ claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America and/or similar provisions of the New York state Constitution on grounds including the following:

- (a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the “beyond a reasonable doubt” burden of proof required in criminal cases;
- (b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon

the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

- (c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendants, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;
- (f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;
- (g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;
- (h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and
- (i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

FORTY-FIFTH AFFIRMATIVE DEFENSE

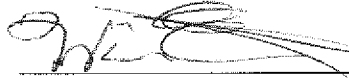
200. Covidien LP intends to rely upon any additional affirmative defenses that become available during the course of investigation and/or discovery and reserves the right to amend its Answer to assert these defenses.

JURY DEMAND

Covidien LP hereby requests a trial by a jury of 12 jurors on all issues so triable.

WHEREFORE, Covidien LP prays that Plaintiffs' Complaint be dismissed and that Covidien LP be awarded its costs, expenses, and attorneys' fees incurred in defense of this litigation and such further relief as the Court deems just and proper.

Dated: September 6, 2013



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**ATTORNEYS FOR DEFENDANT
COVIDIEN LP**

#881006-2

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

----- X
AMALIA FASANO and NICOLA FASANO,

Plaintiffs,

-against-

TYCO HEALTHCARE GROUP LP d/b/a
COVIDIEN; SOFRADIM PRODUCTION SAS;
and John Does 1-50,

Defendants.
----- X

Case No. 1: 13-cv-03083

**COVIDIEN LP'S ANSWER AND
AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT**

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Covidien LP*

To

Service of a copy of the within is hereby admitted.

Dated:.....

Attorney(s) for